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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,597	12/21/2001	Ian Robert Cottingham	0623.0730002/LBB/BJD	2450
26111	7590	05/12/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			PRIEBE, SCOTT DAVID	
			ART UNIT	PAPER NUMBER

1632

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,597

Applicant(s)

COTTINGHAM ET AL.

Examiner

Scott D. Priebe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 20-75 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 20-27 and 30-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/2/02, 10/14/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group XVIII, claims 28 and 29, in the reply filed 4/14/04 is acknowledged. The traversal is on the ground(s) that search and examination of all groups would not impose an undue burden. This is not found persuasive because a search of the elected group does not require a search of any method for using the transgenic mammal nor a search of a mammal where the peptide moiety of the fusion protein is defined. The elected invention does not require that the fusion protein even be expressed, much less secreted in milk. The separate classification, i.e. subclass, of groups I-VIII is an indication that a separate search would be required for these groups. Similarly, a search of the elected invention does not require any search related to that of groups IX-XVII.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-27 and 30-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed 4/14/04.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an

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application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Priority is claimed to application 10/019,153 filed 12/21/01, the same day the instant application was filed. Consequently, the '153 application is not a prior application under 35 USC 120, and the priority claim to the '153 application is improper. Priority is claimed to PCT/GB00/02459 indirectly through the '153 application, which is a 371 application of the PCT application. Consequently, the specific reference to the PCT application does not include the appropriate relationship between the instant application and the PCT application. The priority claim should be amended to delete reference to the '153 application, and to include the relationship between the instant application and the PCT application, e.g. continuation or continuation-in-part.

Information Disclosure Statement

The information disclosure statement filed 5/20/02 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein as reference AN2, EP 0590530 A2 has not been considered.

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References AP1, WO 92/22644, and AR1, Brignon et al., were considered only so far as the contents of their English abstracts, the remainder of these references not being in English.

Drawings

The drawings are objected to because the four sheets of Fig. 2 are not numbered in accordance with 37 CFR 1.84 (u)(1). The sheets should be numbered Fig. 2A, 2B, 2C, and 2D. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: The nucleotide and amino acid sequences shown in Fig. 1 are not identified by the assigned SEQ ID NO, as required by 37 CFR 1.821(d). This objection may be overcome amending either the 'Brief Description' of Fig. 1 (preferred) or Fig. 1 itself to include the assigned SEQ ID NOs.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic non-human placental mammal wherein the DNA molecule is operably linked to a promoter of a gene encoding a naturally derived milk protein, such that when the mammal is female and lactating, the fusion protein is preferentially expressed in its mammary tissue and secreted into its milk, does not reasonably provide enablement for any other embodiments embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are broadly directed to a transgenic non-human placental mammal whose genome broadly comprises DNA encoding a fusion protein, wherein the fusion protein comprises lysozyme and a peptide. The claims broadly embrace embodiments wherein the DNA is not operably linked to a promoter or is not expressed in the mammal, wherein the DNA is operably linked to a promoter and is expressed in the mammal in non-mammary tissue, and wherein the DNA molecule is expressed in mammary tissue of female mammals during lactation, whether expressed in the milk or not.

The only disclosed end-use for the claimed transgenic non-human placental mammal is for production of the fusion protein in milk of a lactating female mammal for subsequent isolation of the peptide linked to the lysozyme fusion partner. All of the guidance in the specification for making and using the claimed mammals is directed to producing the fusion proteins in milk. The specification does not disclose a use for a claimed mammal wherein the

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DNA molecule is not operably linked to a promoter and is not expressed in the mammal. Nor does the specification disclose a use for a claimed mammal that expresses the fusion protein in tissue other than mammary tissue of lactating female mammals and secretion into its milk. There is no evidence of record of a well-established use in the art for the claimed mammals.

Therefore, in view of the breadth of the claims, the lack of guidance in the specification on how to use the claimed mammals wherein the females do not produce the fusion protein in their milk during lactation, and the lack of evidence from the prior art of a well-established use for such mammals, one of skill in the art is left to devise uses on their own. The activity required to develop such uses in the absence of guidance from the specification or prior art is undue experimentation.

Claims 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28 and 29 are indefinite for recitation in claim 28 of “coding sequence having a first segment encoding a fusion partner protein ... coupled to a second segment encoding a peptide.” It is unclear what the coding sequence encodes. Recitation of “coupled” does not define the nature of the relationship between the first and second segment or the fusion partner and the peptide. From the specification, it appears that the first and second segments are linked in translational reading frame, such that a fusion protein comprising the fusion partner and peptide is encoded by the DNA molecule. However, the claim is not clearly limited to this. Amending claim 28 to indicate that the coding sequence encodes a fusion protein comprising the fusion

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partner and peptide, or that the first and second segments are coupled -- in-frame --, would overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 28 and 29 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Akinbi et al. (Amer. J. Respiratory and Crit. Care Med. 159 (3, Suppl. S): A752, Mar. 1999).

Akinbi discloses a transgenic mouse whose genome comprises a DNA encoding a fusion protein comprising rat lysozyme fused to a peptide, residues 278-381 of human SP-B.

This rejection would be overcome by limiting the claims to transgenic mammals wherein the DNA molecule is operably linked to a promoter of a gene encoding a naturally derived milk protein (spec., p. 21) or a comparable limitation supported by the specification, and the fusion protein will be secreted into milk during lactation when the transgenic mammal is female.

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Claims 28 and 29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lee et al., J. Biochem. Mol. Biol. 31 (4): 413-417, Jul. 1998.

Lee et al. discloses a transgenic mouse whose genome comprises a DNA encoding a fusion protein comprising human lysozyme fused to a peptide, the signal sequence of bovine β -casein (see entire reference, especially page 414, col. 1 and Fig. 1).

Claims 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Deboer et al., WO 93/25567.

Deboer discloses a transgenic mouse whose genome comprises a DNA encoding a fusion protein comprising human lysozyme fused to a peptide, the signal sequence of bovine α S1-casein (Example 24, pp. 115-117; Fig. 26).

Claims 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Weaver et al., US 5,993,809.

Weaver discloses a transgenic mouse whose genome comprises a DNA encoding a fusion protein comprising rat lysozyme fused to a peptide from human SP-B. See col. 4.

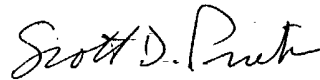
This rejection would be overcome by limiting the claims to transgenic mammals wherein the DNA molecule is operably linked to a promoter of a gene encoding a naturally derived milk protein (spec., p. 21) or a comparable limitation supported by the specification, and the fusion protein will be secreted into milk during lactation when the transgenic mammal is female.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe
Primary Examiner
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